

## REMARKS

Claims 1, 3-8, 10-12, 14-32, 34-35, and 37-46 are pending in the subject application, and claims 1, 37-41, and 43 are independent. By this Amendment, claims 1, 12, 14, 17-18, 20, 24, 29-32, 34-35, and 37-41 have been amended, and claims 43-46 have been newly added in order to provide the Applicant with an additional scope of protection.

The presently-claimed invention relates to hydrostatic delivery systems including a core consisting of a homogeneous mixture of an agent of interest and a hydrostatic couple, where the core is provided in a dosage form selected from the group consisting of a solid compact, an extrusion spheroid, and a capsule filled with a blend selected from the group consisting of a granulated blend, a particulate blend, a spheroidal blend, a compact blend, and a dry blend.

Support for the amendments to claims 1 and 37-41, and new claims 43-46 may be found at least at page 15, lines 21-27, and page 24, lines 4-14 of the present specification. Applicant respectfully submits that no new matter is presented herein.

Applicant submits that none of the cited references, Dresdner, Jr. et al., Rork et al., or Conte et al., disclose or suggest the hydrostatic delivery systems of the presently-claimed invention. Withdrawal of the outstanding rejections under 35 U.S.C. §§ 102(b) and 103(a) are therefore respectfully requested.

Claim 42 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Advisory Action indicated that this rejection was being maintained in spite of the arguments presented in Applicant's Amendment After Final Rejection because the ratios calculated from Applicant's examples "does not represent all points in the claimed range of ratios."

This basis for maintaining the rejection under 35 U.S.C. § 112, first paragraph, is contrary to the law regarding the written description requirement. Applicant is not required to provide an example for every point within the claimed range. Instead, the well-established law regarding the written description requirement indicates that Applicant must "recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 65 USPQ2d 1385, 1397 (Fed. Cir. 2003), *quoting Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991). Satisfaction of written description requirement is measured by

the understanding of a person having ordinary skill in the art. See *Amgen*, 65 USPQ2d at 1397; *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997) ("The description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.").

In the present case, the ranges for the ratios of ingredients used to prepare the hydrostatic delivery system of claim 42 are supported in the specification by an example at the low end of each range, and at the high end of each range. In addition, Applicant has provided several examples of hydrostatic delivery systems having ratios of ingredients that fall at various points within these ranges. One skilled in the art at the time the invention was made would have been able to prepare hydrostatic delivery systems having ratios of ingredients that fall within the claimed ranges using the guidance provided by Applicant's disclosure.

Accordingly, Applicant again submits that the rejected features of claim 42 are fully supported by the specification and the examples set forth therein, and respectfully requests withdrawal of this rejection.

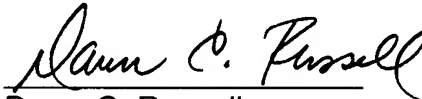
### **CONCLUSION**

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of Claims 1, 3-8, 10-12, 14-32, 34-35, and 37-46, and the prompt issuance of a Notice of Allowability are respectfully solicited.

Should the Examiner believe anything further is desirable in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event this paper is not considered to be timely filed, Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to counsel's Deposit Account No. 01-2300, **referencing Attorney Dkt. No. 026806.00017.**

Respectfully submitted,



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